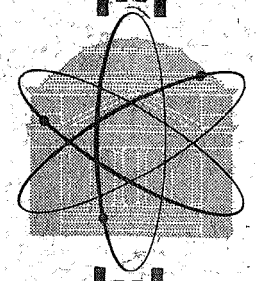
TECHNOLOGY TRANSFER IN BIOMEDICAL ENGINEERING

Final Report
for the period 1 September 1969-30 June 1970
University of Virginia Subgrant under
NASA Multidisciplinary Grant NGL 47-005-014

Prepared for:
Technology Utilization Division
National Aeronautics and Space Administration
Washington, D. C. 20546

Prepared by:
Michael L. McCartney



Research Laboratories for the Engineering Sciences

University of Virginia

Charlottesville

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I. Introduction

The current report summarizes activities of the University of Virginia since 1 September 1969 when a subgrant "Technology Transfer in Biomedical Engineering" under a NASA multidisciplinary grant to the university was awarded to the Division of Biomedical Engineering.

During the period of this report, a mechanism for transfer of aerospace technology appropriate to biomedical problems has been designed and begun to be executed. Problems have been received from each of NASA's Biomedical Applications Teams and are in various locations within the transfer system herein described.

This report concerns primarily the creation of an Applications Engineering Center, the generation of its operational guidelines, and the recommendations for improvements in the transfer system as viewed by the facility responsible for re-engineering technology.

Individual projects are presented mainly for illustrative purposes, since their technical content will be the subject of separate reports.

The following individuals and their departments have been instrumental in assisting the various technical phases of this program:

Michael L. McCartney, Sc.D., Biomedical Engineering

Glenn E. Stoner, Ph.D., Materials Science

Jay Y. Gillenwater, M.D., Dept. of Urology

Cosmo A. Difazio, M.D., Dept. of Anesthesiology

II. Background of Effort

As a means of making available to the medical community applicable aerosapce technology, NASA has established three Biomedical Application Teams (BATeams) at Research Triangle Institute, Southwest Research Institute and Midwest Research Institute. The stated purposes of these teams are to:

1) Increase the return on the national investment in aeronautical and space programs by helping to bring about additional uses of the knowledge in many fields of technology gained in these programs.

2) Shorten the time gap between the development of new knowledge and its broad and effective utilization.

3) Aid the movement of new knowledge across organizational, disciplinary and regional boundaries.

4) Help develop better methods for communicating and applying government-generated knowledge in the private economy.

These objectives are achieved by: identification of the needs of the medical groups or individuals with whom they are affiliated; searches of NASA technology (by literature retrieval and by circulation of problem statements at the appropriate NASA research centers) for information, processes, devices, etc., which can contribute to the problem solution; making available such technology to the problem originators. That this is a workable system is adequately shown in the reports from the BATeams. There are, however, situations in which the technology uncovered is in a form not directly useable by the problem originator. If the investigator lacks the proper combination of background, talent, facilities or personnel to "adjust" the technology to his needs, a transfer is not effected and his problem is not solved.

This technology/problem interface mismatch is the raison d'être for the pilot program at the University of Virginia which is now referred to as the Applications Engineering Center (AEC) of the Division of Biomedical Engineering (BME). The AEC is essentially a small research group whose expertise lies in adaptation, modification and extension of input technology to solve biomedically-oriented problems. A short description of the interests and capabilities of the Division of Biomedical Engineering will indicate why it was chosen for this pilot program.

III. University of Virginia Interests and Capabilities

At the University of Virginia, Biomedical Engineering is a truly interdisciplinary program. It is an autonomous division, having a staff and faculty of 20 full and part time (i.e., full BME appointments and joint appointments with the schools of engineering and medicine). The student body consists of 20 (30 confirmed for Fall 1970) individuals with various backgrounds in the engineering and life sciences, all working toward the Ph.D. in Biomedical Engineering or toward the Ph.D. and the M.D. degrees.

Emphasis in the department is placed on societal needs mediated through ecology, basic physiological research, instrumentation development and systems analysis. Some of the areas of activity are:

1) Definition and function of the mammalian oxygen transport system using models, simulation and controlled experiments.
2) Instrumentation design for in-house use.
3) Development of ride-comfort criteria for public transportation systems.
4) Critical-care monitoring system design; a contract with industry to design and evaluate marketable prototypes.
5) Development of vascular prosthetic material processes--in coordination with the Materials Science Department.
6) Development of artificial limbs--in coordination with the Mechanical Engineering Department.
7) Research for marketable prototypes of various non-critical care instrumentation--in coordination with various departments within the Medical School; funded by industry.

Because of the interdisciplinary nature of most of the above, BME enjoys a healthy working relationship with other departments within the University Community. Materials, facilities, and personnel are frequently shared and consultation on a wide basis is available. In addition, the BME Division is geographically, as well as administratively, close to a large medical teaching center.

One of the goals of Biomedical Engineering at the University of Virginia is the definition and exercise of the role of BME in health care delivery. This role includes basic planning strategy for outpatient health care, inpatient services (particularly critical care and laboratory automation) and delineation of the guidelines for responsibilities of federal, state, and local governments, universities and institutions, and industry and small business in the health care system.

IV. Project Selection

In order to assess the contributions which applications engineering can make to technology transfer, the criteria for problem acceptance by the BATeams must be presented. Although each of the teams has its own limitations and strong areas which influence the type of items it accepts, some general guidelines are common:

1) Problems accepted must have been found to have no solution available in the commerical market.

2) Requests must be discrete and must be defined in terms specific enough to facilitate computerized searching of stored data.

3) Problems accepted must be ones which impede the progress of major, main-line efforts of an individual or organization.

4) Solutions should appear relevant to aerospace technology

After review of the BATeam reports, representatives of NASA's Technology Utilization Division (TUD) and the principals of the University of Virginia AEC designed a set of procedural guidelines to facilitate applications engineering of those projects which had met the above constraints, but could not be solved without further engineering effort.

The initial guidelines were further modified during discussions with representatives from the BATeams and the current version is presented here:

1) Identification of an Engineering Need. This step is performed by the BATeam which identifies a specific end item from a problem or need defined in conjunction with a researcher or clinician. The constraints which apply have been listed above.

2) Definition of Preliminary End Item Specifications. The BATeam documents detailed specifications and technical requirements

for the end item.

3) Preliminary Review of End Item Specifications. An initial review of the end item specifications for the applications engineering candidate project is made by TUD. Their criteria for selection are:

    a) Potential impact of the end item.

    b) Cost of application engineering.

    c) Time anticipated to complete engineering effort.

    d) End item must be in post-conceptual stage of development within NASA.

4) Review of Requirements and End Item Specifications. A final check on the feasibility of the end item and an assessment of the required internal capabilities is made by the AEC.

5) Project Requirements Document (PRD) Preparation. The AEC, with input as necessary from the sponsoring BATeam and the problem originator, draws up a detailed PRD including quantitative and qualitative end item requirements and a time-cost milestone summary.

6) Project Review and Approval. The AEC submits its PRD to the sponsoring BATeam which reviews and forwards it to TUD with recommendations. Upon appropriate action on the recommendations, TUD formally authorizes the AEC to begin work on the project.

7) Project Implementation by the AEC.

8) End Item Delivery. The end item and suitable documentation including engineering and performance specifications are provided to the problem originator via the sponsoring BATeam.

9) Development of Evaluation Protocol. The problem originator and sponsoring BATeam define a set of criteria for objective evaluation of the end item.

10) Evaluation/Testing. During and after evaluation, the problem originator provides appropriate feedback via the BATeam to TUD and the AEC.

11) Documentation of the Transfer by the BATeam.

The guidelines are presented in the above form for compactness and to provide a brief overview of the pilot system operation. It may be instructive to annotate them to further define the mechanism of the applications engineering effort:

1) This has been described in detail earlier.

2) Ostensibly, the preliminary specifications are supposed to provide criteria by which the AEC can assess its abilities to provide the required service. Actually, the specification procedure is a filter: projects which cannot be formally specified are not good A. E. candidates.

3) The review of the preliminary specifications by TUD actually overlaps that of the AEC. This is one of the most flexible areas in these guidelines. In addition, the AEC may be called upon to assist the BATeams in writing the initial specifications. Feedback from the AEC to TUD and the BATeams is essential here to outline the university's capabilities more precisely. Once the program is proved as an acceptable transfer technique, and the principals are more familiar with each other's capabilities and limitations, need for some of this overlap will be minimized.

The number of problems which have been presented to the BATeams have necessitated constraining the Applications Engineering effort to those which will have a significant impact on the medical community if solved. To mediate this objective with a pilot program having limited funds and personnel ($25,000 total annual budget and one half-time engineer with a half-time technician) the projects selected must be restricted to those which have solutions beyond the conceptual level within NASA and must be realisitc in terms of the time and budget available (i.e., should not be research programs in themselves). An examination of the active projects in Appendix A will show close conformity to these constraints.

4) Since staff and funds are limited, and in order to avoid premature growth before the concept is proven, the AEC draws heavily on the time and facilities of other departments within the university. This is, at best, an inefficient process since requests must be worked in around other researchers' priority lists. It is, for an initial program, quite rewarding and suffers only from time delays.

Meetings with the BATeam representatives to discuss A. E. candidate projects and possible candidates have been educational in that each of the principals has an opportunity to learn of the limitations and capabilities of the others. The meetings have also supplemented the principals' knowledge of new products on the market which aids in selection of problems at the BATeam level.

5) The PRD outlines not only the technical specifications of the end item which the AEC intends to produce, but also places the bounds on the AEC's responsibilities. This is the document which specifys the number of items to be made (to avoid open-ended requests) and cites any hazards which may be associated with use of the end item. In the case of items requiring implantation or attachment to human beings, the problem originator assumes responsibility for the end item use. This is justified by the existence of boards (committees) in the research medical centers which approve human experimentation. This is not to say that the AEC has no professional responsibility. Quite the opposite is true. Every effort is made to carefully evaluate materials and techniques used in the fabrications of end items so that the item will meet the stated requirement without introducing additional hazards. In cases where material compatibility tests cannot be documented, the problem originator is notified both through a personal contact from the AEC and through the PRD.

6) The PRD review is intended to catch any misinterpretation which might have occurred between the problem originator and the AEC.

7) When approval is likely and delays in procurement may severely slow the project, the AEC may actually begin to acquire materials and do preliminary work before formal approval. This is one of the several items which are not strictly followed in the pilot program, but should be upon future growth.

8,9&10) Delivery and evaluation cannot be functionally separated so easily as on paper. Frequently, the evaluation protocols will be used by the AEC to prove the end item design before shipment. Similarly, any test procedures devised by the AEC can be used by the problem originator to verify or monitor performance after delivery.

11) The final formal NASA-related function is documentation of a transfer by the BATeam. More will be said of this in the next section.

The guidelines themselves have not proved to be any barrier to effective transfer. However, an examination of the projects in Appendix A will show that there is a great variability of the forms in which problems are presented. The BATeams have not been as careful as they might be in outlining the end item requirements, depending heavily on questions from the AEC to complete their specifications. The necessity for such contacts means that the AEC does not have a complete set of end item specifications in a single document.

Possible mislocation of the additional specification is not the only hazard of this method of information transfer. A more severe problem, that of lack of design freeze, does result. This becomes apparent in problems such as KU-35, the Respirometer for Anesthesia. The original problem statement is given in the Appendix, but subsequent requests for additional information resulted in changes in the specifications. For example, the following dialog (by mail) is offered:

AEC: Is digital readout of liters/minute and breaths/minute adequate or must the computation liters/breath be made?

BATeam: The most useful readout would be liters/minute; liters/breath would be nice but not necessary.

AEC: For which of the following

total volume

flow rate

breath rate

others

is analog output required?

BATeam: Total volume.

AEC: If this is a closed anesthesia system, is bidirectionality really necessary? Exhaust line would seem to be adequate.

BATeam: Exhaust line will be adequate.

This is not to be taken as a criticism of the BATeam per se, since the changes in specifications came from the problem originator. Changes of this type do, however, indicate a need to tighten the format of the preliminary specifications to be submitted to the AEC if a PRD is to be written within a reasonable amount of time. The problem is not limited to a single BATeam since similar events accompany the other items in Appendix. A.

V. Achievements

To date, most of the results of the applications engineering effort have been intangible. The program was started late in September 1969 rather than in April as originally intended. The initial months of the program were used to define the foregoing objectives and to generate guidelines for attaining them. Once the AEC and TUD were satisfied with the tentative structure, a meeting was called to acquaint the BATeams with the A. E. effort and to solicit projects for it. This initial meeting (and subsequent ones) was primarily educational in that the guidelines were presented to the BATeams for their critical appraisal, and the team members were acquainted with the University of Virginia and some of the people administrating and working in the program. This orientation was necessary to assist the BATeams in selection of initial problems.

Many of the initial problems were disqualified because they were not in the post-conceptual phase of development and others because commercial solutions (not known to the problem originator or the BATeam) were available.

Of the projects selected, one is in the fabrication stage (the prosthetic urethral valve), four are in transitional stages, requiring further specification before a PRD can be completed and one is in the PRD writing stage.

In addition to the physical production of end items, there are several intangible benefits which have resulted from the UVa.-NASA liaison.

1) We have created a potential for major contribution to the health care delivery system (subject to some of the constraints indicated in the section on recommendations). Technology from the aerospace field, al-

ready paid for and used for its intended purpose, appears to possess an economy and a quality more consistent with the needs of clinical medicine than industrial de novo research to achieve the same end.

2) NASA support has allowed the BME division to add modestly to its staff and to draw on the talents of some of its more imaginative graduate students for assistance in solving some of the application engineering problems.

3) Requirements of the A. E. candidate projects have forced BME at UVa. to become more extroverted, and have improved communications with other departments in the university.

4) External communication opportunities (e.g., NASA, NIH, BATeams and problem originators) have been enhanced, resulting in greater outside interest in our BME program.

5) TUD has begun to compartmentalize its thinking about impact areas to see if there are any particularly fertile areas in the health care system for technology transfer. This is evidenced by the grouping of the BATeam projects into the following areas:

1) Communicable Disease, detection and prevention (3)
2) Heart Disease, detection and treatment (23)
3) Cancer, detection and treatment (17)
4) Renal Disease, detection and treatment (13)
5) Respiratory Disease, detection and treatment (14)
6) Dental and Oral Disorders, detection and treatment (16)
7) Multiphasic health screening, clinical diagnosis (36)
8) Rehabilitation Medicine (42)
9) Artificial Organs (16)
10) Organ Assists (2)

11) Mental health (16)

12) Ecology (8)

13) Health Care Cost Reduction (4)

14) Remote health care services (1)

15) Provision of more/better medical and paramedical personnel (3)

16) Infant Mortality reduction (25)

17) Surgical procedure/technique improvement (15)

18) Basic medical research (97)

19) Miscellaneous (12)

It is immediately obvious that these categories are not unique and that considerable overlap occurs. As more problem areas are exposed through the BATeam efforts, this list is expected to change in both content and length. Even in its present form, this list is useful for attempting to recognize broad areas to which aerospace technology transfer may be heavily applied. The numbers in parentheses after each category indicate the number of BATeam projects which are in the designated area.

Single areas of importance are heart disease, cancer, multiphase screening, and rehabilitation. This is not surprising since these represent the largest efforts on a national scale. Although aerospace technology can make contributions in most of the 19 problem categories listed, it is instructive to realize that those problems with the largest political as well as medical impact stand the greatest chance of exposure. Such recognition is necessary, however, to perpetuate the transfer system.

VI. Recommendations and Comments

Given the current structure of the technology transfer system and the potential contributions to the improvement of national health care which can be mediated by it, there are several barriers to maximal effectiveness apparent:

1) The BATeam efforts are small, operating with a limited staff which heretofore was not active in biomedical areas. This automatically delays their capabilities to judge the merits (in contradistinction to the technical feasibility) or problems presented to them. As a result, the teams may find themselves spending time trying to transfer inappropriate technology. An example of this sort of situation is the appearance of electronic stethoscopes which are occasionally superb from a technical point of view, but are abysmal failures in the market place.

2) The BATeams, as a result of TUD structure and organization, must be responsive to the stated needs of the medical community. They are not in a position to propose problems as well as solve those proposed from outside. One justification for maintenance of this position is the avoidance of competition with other agencies such as NIH, FDA, and the university researchers themselves. For the time being, this is an acceptable argument, but if the technology transfer goal is improved health care, it may become necessary to consider a competitive position.

3) Current TUD management philosophy does not provide for selection of problems by the BATeams primarily keyed to relative impact on the health care system. This is a position which can be handled by a bifurcation of efforts: one oriented toward those

high-impact areas of national interest and one which handles the basic research and miscellaneous problems. This would be feasible if and only if sustained communication can be achieved between the two efforts.

4) The Applications Engineering effort is small, of necessity until the feasibility is clearly demonstrated. This is a self-remedying problem, since productivity and growth are in a positive feedback loop.

5) The accomplishments of BATeams and AEC reach the medical community by diffusion alone. It is unfortunate, but true, that technology in the medical community is frequently relayed by anecdote. This makes objective judgment of technology almost impossible.

The lacking factor in the technology transfer system is an effector mechanism for ensuring that high-impact items reach the health-care system and do not stop at the problem originator or his institution.

In general, industry is reluctant to produce limited-market high-risk items which are public domain. As the AEC, the University of Virginia has also generated contracts with industry to have medical instrumentation produced which was developed with public funds. A similar relationship for the technology transfer program would seem to be a logical method for obtaining optimal distribution of significant end items.

The University of Virginia is in the unique position of having the mechanism for transfer from public to private to public interests and of having a facility in which new products/technology can be tested. This testing facility includes both medical and

technical evaluations, putting the university in a good position to exercise a quality control function on devices developed here.

We would recommend that the University of Virginia AEC be allowed to use these channels through industry to expedite use of significant re-engineered technology obtained through NASA.

6) In order to facilitate writing of the Project Requirements Documents, the BATeams must try to obtain complete specifications on the end item prior to presenting them to the AEC through TUD. As noted in the previous section, the requirements in their written form are somewhat sketchy and are not all contained in a single document.

7) It is worth noting that the National Academy of Engineering is examining the Technology Utilization program to make recommendations for the directions it should head within biomedical applications.

APPENDIX A

Active Applications Engineering Projects

A Prosthetic Valve for the Urinary Tract
(Summary of End Item Specifications)
WF-3

Description of Problem:

A number of different injuries and diseases can result in loss of control of urinary function. Victims of congenital defects, neurogenic bladder diseases, stroke, and multiple sclerosis, as well as war and automobile accident casualties, frequently experience bladder and urethral malfunctions. These malfunctions usually involve an inability to relax muscles which close the urethra; i.e., the passage through which the bladder is emptied. This condition generally results in gradual deterioration of the bladder, infections of the urinary tract, and in some cases damage to the kidneys and subsequent death. This condition is the most frequent cause of death of paraglegics. In treating patients who cannot control urinary function, it is important that the bladder be allowed to fill and then be emptied rapidly every 3 to 4 hours. This periodic functioning allows the muscles of the bladder to be exercised and, as a result, to remain healthy. One approach that has been taken is to attach electrodes to the bladder muscles so that contraction of the bladder can be electrically induced by the patient. This electrical stimulation unfortunately also induces contraction of muscle groups--i.e., sphincters--which close the urethra. As a result, fluid pressure inside the bladder becomes dangerously and painfully high.

A valve which can be implanted in the urethra and can be controlled by the patient is needed to successfully treat the loss of urinary function. In cases where bladder muscle is healthy when the valve is implanted, the bladder would contract when the valve is opened without stimulation due to the inherent elasticity of healthy muscle tissue. If bladder muscle deterioration has occurred, electrical stimulation can be used simultaneously with opening of the valve without causing excessive internal pressure.

Functional requirements and constraints on the configuration of the prosthetic urethral valve are as follows:

(1) The size of the valve must be such that it can be implanted in the space shown in Figure 1. It is desirable that the valve be cylindrical with a maximum diameter of 2.5cm. (Small rigid tubes will pass through the physiological valve--sphincter vesicle and external sphincter--shown in the figure so that fluid is held in the bladder only by the prosthetic valve.)

(2) The patient must have manual control of the valve.

(3) The valve must remain closed when exposed to a maximum differential pressure of 150 cm of H_2O.

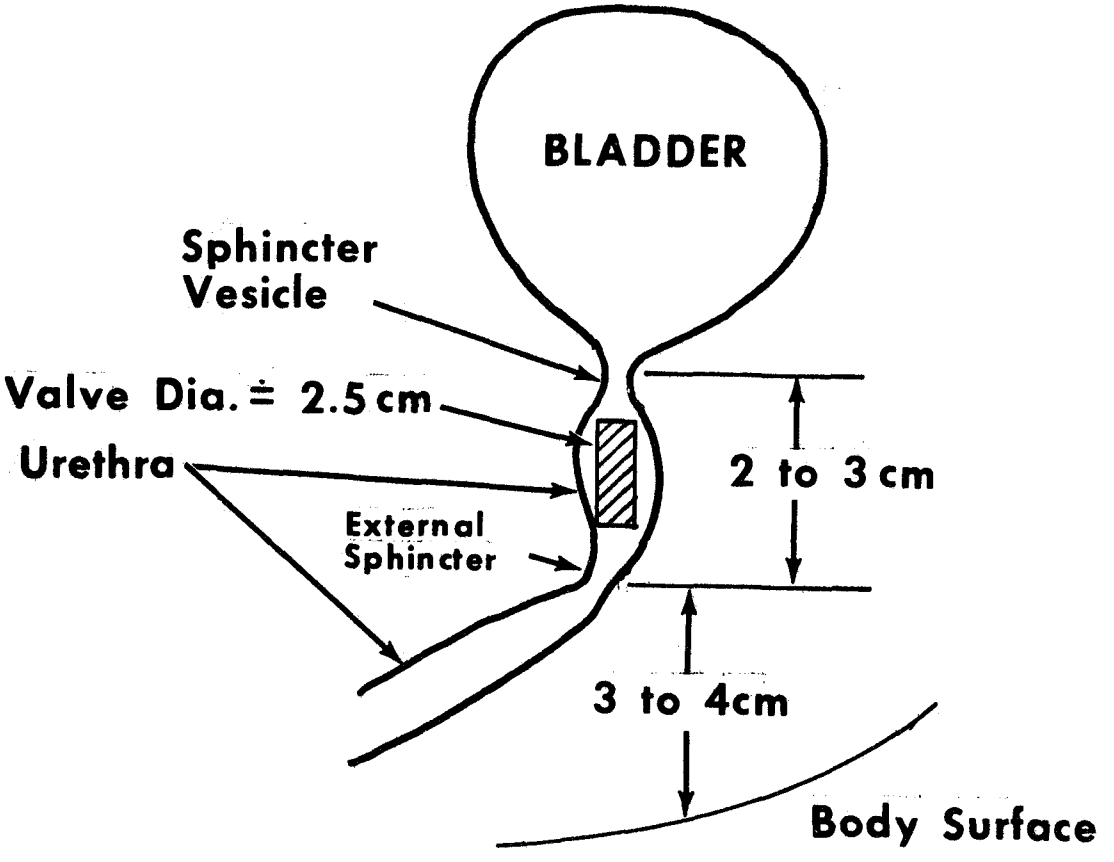
(4) The valve cannot be controlled through the use of wires or tubes passing through the skin.

(5) Functional reliability is an absolute necessity.

(6) All surfaces of the valve which are exposed to tissue must be a physiologically inert material, such as silicone rubber.

Description of Solution:

The solution to the requirement for a prosthetic urethral valve is illustrated in Figure 2. Basically, the prosthesis is a completely im-



Accumulation of urine: 2-3 ml/min, 1200-1500 ml/day
Total capacity of bladder: 500 ml
Initial pressure in bladder when contracting: 40 cm H_2O
Average flow rate in urethra: 20 ml/sec
Time to empty bladder: 20-30 sec

Figure 1 - Prosthetic Urinary Valve

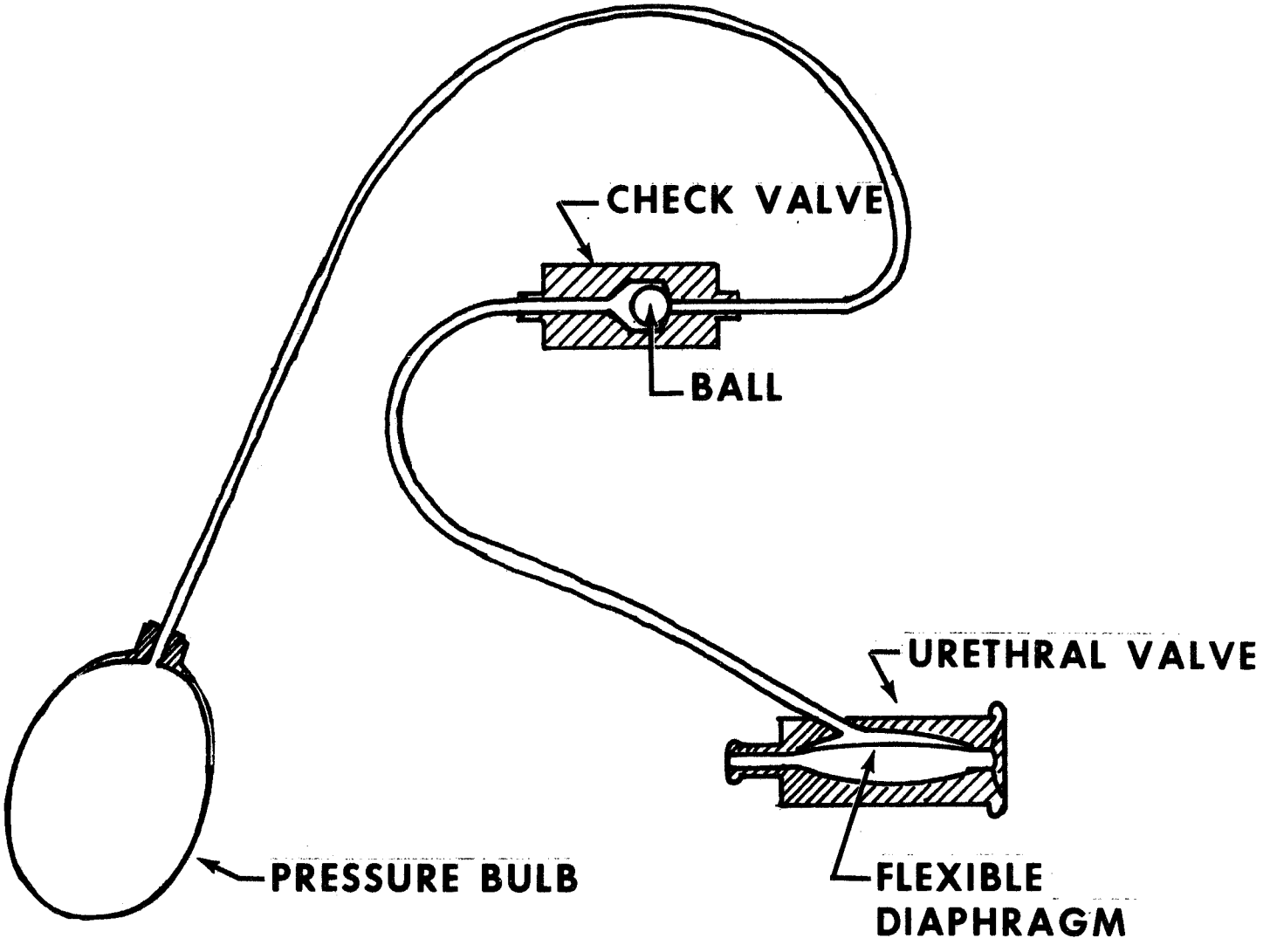


Figure 2 - Cutaway of Urinary Valve

planted and closed hydraulic system with two stable states. One state corresponds to the valve being closed; in the other state the valve is open. The open and closed states of the prosthesis are selected by the patient. This is done simply by pressing with the hand on one of two positions on his body. A more detailed description of the operation and construction of the valve is presented in the following paragraphs.

The valve essentially consists of three elements: the urinary valve, a check valve, and a pressure bulb, connected by flexible tubing. The urinary valve consists of an inflatable, rubber diaphragm fitted into a polystyrene tube. The polystyrene tube restrains the diaphragm, so that when the diaphragm is inflated the tube is completely sealed. In addition, the polystyrene tube is configured to allow the urethral valve to be securely attached in place.

The check valve, which lies between the urinary valve and the pressure bulb, serves two functions. First, it is a one-way check valve placed so that when the urethral valve diaphragm is inflated, the check valve is closed, pressurizing the diaphragm and keeping the urethral valve closed. Second, the check valve is specially designed so that slight deformation of the check valve, achieved by applying a small force to the body of the valve, causes the check valve to open. This releases pressure on the diaphragm opening the urethral valve. The body of the check valve is constructed from silicone rubber with a rigid ball preloaded on the seat. Slight pressure applied to the body of the check valve deforms the valve seat so that, instead of having a circular cross section which can be sealed by a ball, it becomes an essentially elliptical cross section through which fluid can leak around the ball releasing pressure on the urethral valve.

The pressure bulb is used to apply pressure to the diaphragm of the urethral valve, thus closing it. Both the check valve and the pressure bulb can be implanted beneath and operated through the skin of the patient's side. The two are separated by a flexible tube approximately four inches long to achieve unambiguous separation of function.

This system fulfills all of the requirements of the desired prosthetic urethral valve and yet retains a simplicity which should lead to reliable operation. Several features of the valve are particularly important:

1) The entire system can be easily coated with silicone rubber and rendered physiologically inert.
2) No external connections are required to actuate the valve. The simplicity of the check valve permits voiding using only the pressure of one finger on the skin at the appropriate point. Reinflation of the diaphragm, when voiding is complete, is easily accomplished by pressing with the palm of the hand over the bulb which is implanted underneath the skin.
3) Because of the simplicity of the system, it should be a highly reliable device. Should the system fail resulting in loss of pressure to the prosthetic urethral valve, the urinary track would remain open. Thus an emergency operation would not be required, as would be the case if the valve could fail in a closed position.
4) Inflation and deflation of the diaphragm in the urinary valve will result in flexing of the exterior surfaces of the valve which come in contact with the urine. This flexing action will tend to break off any incrustation that might occur, keeping the closing surfaces of the valve clean.

Successful Searching Method:

Response to Biomedical Problem Abstract WF-3, "Prosthetic Urinary Valve".

Source of Solution:

Mr. Kirby W. Hiller, NASA Lewis Research Center, Cleveland, Ohio, suggested the solution in a response to Biomedical Problem Abstract WF-3. His suggestion was based on a simple type of valve which had been used at the NASA center for valving manometer tubes. Significant modification and reengineering were required in completing the transfer. This was accomplished by the Biomedical Application Team in collaboration with the medical investigator.

Benefits to be Derived from Transfer:

The researcher who posed this problem treats an average of 12 new traumatic paraplegic patients every year. Each of these would benefit from the prosthetic urethral valve. It is estimated that approximately 100 new patients per year in North Carolina would benefit from the device. In addition, loss of urinary bladder function results from other causes as well. For example, children with congenital defects, patients with neurogenic bladder diseases, stroke victims, and multiple sclerosis victims frequently experience urinary bladder malfunction. It is estimated that approximately 15,000 new patients every year could benefit from use of this device.

Questions to be considered in Documenting Application Engineering Requirements:

1. For what purpose is the item to be re-engineered required?

   Prosthetic urethral valve.

2. How does the item act to solve the medical problem?

3. What is the reasoning behind the approach utilizing the item?

   Remotely actuated, hydraulic valve which permits a completely implantable system that can be actuated by the patient with his hand.

4. Were other approaches tried?

   Yes, the researcher has designed six or seven other valves which have all been mechanically actuated. The valves were not satisfactory because a simple means of actuating the valves could not be evolved.

5. In what stage of development is the item now (concept, designed breadboard, prototype, etc.)?

   Designed Breadboard

6. Is a change in this status anticipated in the near future?

   Uncertain

7. What amount and type of specification blueprints and other technical support data are available on this item now? Can operational specs be defined?

   Operational specs and mechanical dimentions can be supplied

8. If not complete, when can all data be available?

9. Are there critical dimensional constraints on the item or parts thereof (volume, weight, size, etc.)? How critical are these constraints?

   Yes, dimensions in attached documentation represent maximum useable dimensions of the unit.

10. Are there other constraints on the item (sterility, materials, shelf-life, etc.)?

    Bio-compatible materials must be used to cover the entire valve assembly.

11. Other than standard electronics shop parts and equipment, what will be needed to fabricate the item? To test the item?

    Special molds must be designed or special fabrication techniques developed.

12. How much of the re-engineering to be done is developmental and how much is strict fabrication?

    Mostly fabrication

13. What type of communication is envisioned between the problem originator the team and re-engineering facility?

    Specifications, diagrams, telephone contracts, etc.

14. How much testing is required at the re-engineering facility?

    Researcher will perform testing.

15. Is the investigator prepared to utilize the specified end item immediately upon delivery? If not, when?

    Tests must be completed by the researcher to his satisfaction before the unit can be implanted.

Respirometer for Anesthesia
KU-35

Description of Problem:

During surgical anesthesia it is essential that the respiratory state of the patient be under continuous observation. One of the most important considerations is the volume of gas moved per breath. A second consideration is the volume moved per minute. A readout which would provide both of these plus instantaneous flow would be desirable.

The composition of gas being measured may vary considerably as the anesthetic varies the composition of the anesthetic mixture.

Consideration should be given to the fact that explosive mixtures may be flowing through the meter and that it may be exposed to appreciable concentrations of halogenated hydrocarbons.

The flowmeters would be used in a closed-circuit anesthesia machine in which the machine gas flow directly represents patient flow.

The desired flowmeter should be sensitive to flows in the range of ±5 liters/min. It should read flow independent of temperature, humidity, and general gas composition. The pressure drop associated with maximal flow should be on the order of 1-2 cm H_2O.

Potential Solution:

A potential solution for this problem is the FRC modified Wright Spirometer, described in Technical Note TND-4234. There is some question whether the FRC unit is sufficiently accurate for flows at 5 liters/min, particularly intermittent flows. However, the medical investigator has

expressed a desire to evaluate the unit if it were available. No unit is available at FRC for this purpose.

ERC is working on their own modification of a Wright Spriometer. No reports on this unit are available. This unit is reported (verbally) to be more sensitive than the FRC unit. The Massachusetts General Hospital is presently evaluating the ERC unit. It seems to be advisable to await the outcome of their evaluation.

Statham Instruments, Inc., is working on an ultrasonic spriometer which is reported to be far superior to either modified Wright Spriometer. This instrument is also a possible solution to the problem. However, the instrument is not yet on the market and no available date has been announced.

Increased sensitivity was gained in the ERC design by adding more light interrupters to the rotary vane. This modification should be incorporated. James Anliker must be consulted for the details.

The internal light source (as shown in TND-4234) was later replaced by FRC with fiber-optics to minimize combustion hazard. This modification is described in NASA Case No. FRC-10039. Additional details concerning physical layout will probably be required from FRC.

The FRC electrical drawings do not completely describe the instrumentation. Two drawings, amplifier and photo-electric pickup head show the heart of the electronics. In addition, an output function is required which will read out breath volume and average volume per minute. This requires an integrator or counter to accumulate the pulse output of the amplifier, and output for strip-chart recorder.

A Respiration Alarm
IRM-23

I. Problem Definition and Justification:

A. Specific Problem

The Goldwater Memorial Hospital of the New York University Medical Center operates one of the largest respirator centers in the United States. Users of these respirators are permanently disabled, e.g., stroke victims, paralysis victims, and others permanently unable to respire themselves as a result of accident or disease. This means that the respirators must be used on the patients continuously and for long periods of time. The respirators have battery-operated alarms connected to their mechanisms which function when the respirator becomes disabled. The alarms are not foolproof, however, because the alarm system itself is subject to failure. Circuit failures can, and do, occur. In addition, the batteries that power the alarm system can become depleted without the knowledge of the nurse, and maintenance personnel must be relied on to insure that the batteries are always adequate. The result is that nurses do not fully trust the alarm system. This results in closer surveillance by the nurses and, correspondingly, requires more of their time. In addition, there have been reported cases in which patients have died when respirators with faulty alarms became inoperative before medical personnel had become aware of the situation. As a result, a separate alarm system is desired, independent of the respirator alarm, which can sense when a patient is not being respired.

It is desired that the alarm sensor be attached to the patient and monitor some parameter that is a direct index of whether the patient is being respired or not. Sensing of even a mechanical parameter, such as change in volume of the chest with respiration, would be acceptable.

B. Use

The alarm system would be used on patients which require artificial respiration continuously.

C. There would be a significant savings in nurses' time. In addition, serious complications resulting from undetected failure of the patient to be respired could be eliminated.

D. This is a chronic problem in hospitals where patients must be artificially respired continuously. Respirator manufacturers are aware of the problems and have provided alarms. Unforunately, the performance of these commercial units has been such that they are rejected and generally not used.

II. Proposed solution:

A. Solution based on Aerospace Technology

1. A respiration alarm unit that was designed at Ames Research Center was identified as applicable to this problem as a result of a NASA Tech Brief (68-10365) and its Technical Support Package.

2. Ames Research Center. It was developed as a respiration alarm for infants.

3. Its capabilities fully meet all the requirements of this application. In fact, some simplification by eliminating the telemetry portion of the system can be achieved should it prove desirable from an economy standpoint. This trade-off can be knowledgeably made when accurate costs are available.

B. Other Potential Solutions

1. Yes.

2. A much cruder device has been considered by the researcher as the result of a Russian document furnished by the Biomedical Application Team. It cannot be used in as many different situations nor is it considered as reliable as the Ames unit.

3. Yes. The researcher prefers the Ames unit for the reasons mentioned above.

III. Engineering Requirements:

1. Engineering Specifications - The alarm unit must be reliable. It must be sensitive enough to detect loss of respiration, but it must not be so sensitive that frequent false alarms are given. If frequent false alarms are given, the unit will be turned off or ignored, and it will serve no useful purpose. Necessary attachments to the patient must not be so bulky as to cause the patient discomfort. In summary, simplicity, reliability, and low false alarm rate are primary requirements.

2. Diagrams (refer to Tech Brief back-up package).

3. Environmental Constraints - None which have been considered in the Ames design.

4. None

5. Dr. McCartney would be able to make the best estimate of cost, because detailed schematics and mechanical drawings are available on this unit.

A Fluid Pressure Calibration System
WF-56

I. Problem Definition and Justification:

A. Specific Problem

A system which can be used to calibrate pressure transducers employed by researchers and clinicians in their investigative and diagnostic procedures is required.

At the Bowman Gray School of Medicine there are a large number of pressure transducers of varying manufacture and design that are employed by investigators in their research program and by clinical personnel in the diagnosis and treatment of patients. A significant question that recurs with great frequency is "Has my pressure transducer maintained calibration or is it now inaccurate?" Many of these transducers are inherently fragile, nonetheless they receive severe handling and are exposed to harsh environments. Consequently, the accuracy of a transducer is usually uncertain unless it is calibrated before each use. Since a calibration facility is not available at Bowman Gray, no doubt many transducers are used whose accuracy is no longer within specification.

To alleviate this situation, the researcher desires to establish a calibration facility where the staff and faculty members of the Bowman Gray School of Medicine can determine the accuracy of the pressure transducers that are employed to obtain measurements in research and clinical practice.

B. Use

The pressure calibrator unit would be used to calibrate pressure

transducers which are employed by researchers and clinicians in their investigative and diagnostic procedures.

C. No such facility is now available at Bowman Gray School of Medicine. Presence of such a calibration facility would accomplish three things. First, investigators would have greater confidence in their instrumentation if a direct calibration check can be made before use. Second, considerable investigator time would be saved over other methods by which the investigator can confirm the accuracy of his pressure transducer. Finally, the possibility of the generation of false data resulting from improperly calibrated pressure transducers would be eliminated.

D. This is a common problem to many medical schools and hospitals.

II. Proposed Solution:

A. Solutions based on Aerospace Technology

1. The solution is a fluid pressure calibration system. The solution was found as a result of routine manual searching of STAR abstracts.

2. It was originally developed at the U. S. Air Force School of Aerospace Medicine, Brooks Air Force Base, Texas. It was developed to solve the same general type of problem as that at Bowman Gray.

3. As described in publication N68-25062 and a document from the open literature, the unit has all the capability necessary to solve this problem.

B. Other Potential Solutions

1. Another approach to this problem has been found in the open literature, but it is not available.

2. The other system, designed in England by C. D. Shelton and B. W. Watson is basically a modification of the approach employed by the researchers at Brooks Air Force Base. It appears from the paper that the English unit may be superior in performance; however, it is likely to be more difficult to fabricate.

3. Yes, he has contacted the English authors and tried to obtain further information and to ascertain if the unit will be commercially produced. The information was not forthcoming, probably because they are entertaining the thought of manufacturing the unit commercially. No concrete information about potential availability could be obtained.

III. Engineering Requirements

1. Basically, the calibration unit would consist of a pressure wave generator, an accurate standard transducer, a pressure chamber, and appropriate manifolding. The fluid within the pressure chamber can be distilled water. Means of eliminating air bubbles in the chamber is necessary, because air bubbles seriously affect the pressure generated by the pressure generator. The pressure generator must be capable of generating fluid pressures in the pressure chamber from near zero to approximately one atmosphere of pressure (760 mm Hg gage). Frequency response of the pressure generator with a given pressure output should be constant (±5 percent) over the frequency range from 1/10 hertz to 150 hertz, applied as a 25-50 mm Hg sinusoid on a 50-700 mm Hg static level.

If the output frequency response of the pressure generator cannot be held to ±5 percent over the frequency range from 1/10 hertz to 150 cycles, then a calibration curve for the pressure generator is accept-

able. This, of course, is not as desirable as a constant frequency response.

2. Types of systems to be calibrated: primarily Statham P23 Series transducers with cardiac catheters and needles.

3. Environmental Constraints - Ambient temperature expected to be 74 ±4°F. Sterility is not required.

Improved Techniques for taking EEG
in Infants and Small Children
SWC-1

I. Problem Synopsis:

The investigator is perfecting a technique for using the EEG to test hearing of small children. Today thousands of children classified as mentally retarded are believed to be suffering not from mental retardation, but rather from hearing difficulties which have cut them off from auditory interchanges with environment. Such interchanges are needed to develop their intellect. The investigator is convinced that if hearing defects can be identified early in infancy and appropriate remedial measures initiated (e.g., hearing aids), many youngsters can be prevented from becoming functional mental retardates. The investigator has developed instrumentation to provide averaged EEG signals during periods of auditory stimulation, which quite effectively reflects whether a child hears when such stimuli are administered. The greatest difficulty is in securely affixing the EEG electrodes to the infant's or young child's head. They tend to tug at the electrodes and frequently yank them off, disrupting the screening procedure. What is needed is an instrumented helmet, with EEG electrodes in place. A helmet, particularly if equipped with earphones for administering the auditory signal, would substantially assist in identifying hearing defects in young children who cannot verbally communicate information regarding whether--and to what degree--they hear an auditory stimulus.

II. NASA Technology Considered as pertinent for Applications Engineering to solve the Problem:

NASA has developed a helmet system for broadcasting electroencephalograms of the wearer. The unique electrodes involved, if incorporated into an audio helmet fitting infants and small children, would solve the important problem described above.

III. Problem Definition and Justification:

A. What is the specific problem which the applications engineering project would solve?

Solution of the problem would provide a means of accurately testing the hearing of infants and small children who are unable to verbalize a response regarding whether or not they heard an acoustically presented stimulus.

B. How would the problem originator make use of the end item?

He would use it as part of his technique for testing the hearing of infants and small children, which is based upon the use of modified, conventional EEG equipment.

C. What are the medical and/or social benefits of solving the problem or contributing to its solution?

Today, thousands of children classified as mentally retarded suffer not from mental retardation but from hearing defects which have cut them off from interaction with their environment. Perfection of the EEG hearing analysis technique will permit such children to be identified and given appropriate remedial assistance.

D. Are there organizations and/or researchers other than the problem originator which are either (1) aware of the specific problem to be

solved, (2) aware of the proposed project or, (3) engaged in a related project?

There is general recognition of the relationship between hearing defects and retardation of intellectural development. However, Scott-White Clinic and Hospital is conducting the only known investigation using the EEG to test auditory perception.

IV. Proposed Solutions:

A. Solution based on aerospace technology

1. What is the areospace solution applicable to the problem and was it identified?

NASA Tech Brief 66-10536 describes a helmet system for monitoring EEG, which features a unique electrode that does not require cementing to the scalp. The helmet is placed on the subject's head and contact made without difficulty. This helmet would prevent the infants and small children from tearing the electrodes away. The NASA EEG helmet, modified to provide for auditory input as described in Air Force Publication ARL-TR-69-17. "A closed System Audio Helmet for Monkeys" (6571st Aeromedical Research Laboratory) will provide a solution to this important problem. Both items of aerospace technology were identified as a result of Biomedical Application Team awareness of existing NASA technology.

2. Where (and for whom) was it originally developed and for what purpose?

The EEG helmet was developed by NASA AMES for obtaining EEG's of pilots and astronauts performing tasks under stress.

The closed system audio helmet was developed to determine auditory sensitivity in primates by the New Mexico State University under contract to the U. S. Air Force (Contract No. F29 600-67-C0029, Project 6893).

3. What are its current capabilities and limitations relevant to the problem?

The two items as they stand will not solve the problem: the NASA EEG helmet is for adults and has no earphones; the USAF audio helmet has no provision for EEG electrodes. Combining the two items of aerospace technology will permit provision of a solution to the problem.

B. Other Potential Solutions

1. Are there other potential solutions, aerospace or non-aerosapce, which are currently available?

None have been identified.

2. If so, what are they and what are their advantages and limitations relative to the problem and the proposed aerospace solution?

Not applicable

3. Has the problem originator been made aware of them and, if so, what were his reactions?

Not applicable

V. Engineering Requirements:

Describe the nature of the adaptive engineering effort which may be required to produce desired end item, including:

(1) Detailed engineering specifications

Basically, the task involves taking the NASA EEG helmet and

modifying it so that it will (1) be useable with infants and small children and (2) feature a means for introducing auditory stimulation, such as described in the U.S.A.F. document. The NASA EEG helmet comes in three sizes; and by selection of liner size and length of replaceable sponge, it may be possible to adapt the existing helmet to the smaller head configuration of the intended users. Judgements regarding the extent of adaptive engineering can best be accomplished by obtaining one of the NASA helmets for Dr. McCartney to evaluate. The modification required would seem to be relatively straightforward.

(2) Diagrams/drawing if required

Appropriate diagrams are shown in the attached publications.

(3) Environmental constraints, e.g., biocompatibility with specific systems, tissues, etc.

None

(4) Any other pertinent restrictions or constraints.

None. The audio characteristics specified in the USAF publication (AEL-TR-69-17) are acceptable, as are the EEG provisions specified in NASA Tech Brief 66-10536.

(5) An estimate of the manpower resources required.

Providing one of the existing helmets can be made available by NASA (the smaller size), modification could probably be accomplished with two weeks or less of man effort. Some guidelines are suggested by the audio helmet fabrication effort: the cost of fabricating the helmet totaled $11.50, including $4.50 for the speakers. The NASA helmet features special electrodes which have already been developed which should greatly reduce the manpower resources required to accomplish the re-engineering task.

APPENDIX B

Project Requirements Documents

Project WF-3
Prosthetic Urethral Valve

I. Brief Description of Problem:

Urinary Retention or urinary incontinence, which can occur as a result of injury to the lower urinary tract or to the spinal cord, have a common need for a controllable valve. As described in the RTI report on problem WF-3, a piece of NASA-related technology appears applicable to the prosthetic urinary valve problem. The NASA valve, in its original form, met a desired criterion of being completely implantable, requiring no extracorporeal communication either through the skin or the urethral meatus. The design also reasonably insures that the likely failures which can occur (e.g., from flexure fatigue) will leave the urethra open, thus obviating emergency surgery for correction.

The valve system proposed in this report is a considerably simplified modification of the NASA valve and it is reasonable to assume that further simplifications to expedite fabrication will occur during the prototype work.

II. Elements of the Proposed Solution and Their Operation:

A. The Urinary Valve - The urinary valve consists of a flexible thin-walled tube within and reflected over the ends of a rigid tube. A side port in the rigid tube allows pressure to be applied to the outer

circumference of the inner tube. Note that a given control pressure will hold the valve closed under a larger intraluminal pressure than it can operate against during patency. The flaccid inner tube will collapse quite easily into a flattened cross-section when sufficient control pressure is applied. This presents essentially two parallel flat plates to the control pressure, held together by a force $F_c=AP_c$, where A is the area presented to the control pressure, P_c.

The intraluminal pressure, if applied after the urinary valve is closed (as would be the case immediately after completion of voiding), will be exposed to a surface area A_u which is much smaller than that to which the control pressure is exposed. The ratio of these two areas will determine the effective amplification of the control pressure.

B. The control valve, placed between the pressure bulb and urinary valve, will be essentially unchanged in principle from the original NASA design. When construction actually begins, however, it will be subject to the same simplification process that the urinary valve has undergone. It may also be more feasible, from both a fabrication and a surgical point of view, to make the control valve integral with the pressure bulb. The valve should hold an occluding control pressure for at least 8 hours without significant leakage (indicated by incontinence).

C. The pressure bulb, subcutaneously implanted over a bony prominence (e.g., the anterior edge of the Os ilium), must be capable of generating sufficient pressure to occlude the urinary valve to contain the maximum expected intraluminal urinary pressure.

III. System Requirements:

A. Controlled Pressure Range - Consultation has indicated that the maximum urinary pressure is expected in patients with spastic bladder

and that this pressure is about 100-150 cm H_2O (normal voiding usually requires approximately 50 cm H_2O before the sphincters open). The lowest pressure will be present in those patients with a flaccid bladder, having only gravity draining capabilities (or manual pressure on the bladder).

Our constraints are then that the valve must be capable of holding a 100 cm H_2O pressure and must be made patent by a minimum draining pressure of 5mmH_2O.

B. Control Pressure Range - This is less well defined than the controlled pressure since it will depend on the stiffness of the urinary valve and on its exact dimensions; more pressure for the smaller valves than the larger ones. Worst case may be assumed to be 100 cm H_2O for the case in which no amplification is attainable. Experiments with our models will provide better information than can be stated now.

C. Dimensions - See Drawings and Tables for proposed valves.

D. Materials - It is considered important that all items be made of bio-compatible materials rather than simply be coated with them. There are several materials which can be used for the inner tube, silicone rubber being the most obvious. Documented use of the medical silastics in the urethra is encouraging since minimal inflammatory response is observed. Buildup of concretions apparently is more closely related to sterility of the urine than to materials within the urinary system. Construction of the urinary valve is such that it is feasible to remove any concretions with a probe if necessary.

Currently, we are trying to obtain some samples of Lycra (a duPont trademark) tubing to test for this application also. It has proved quite durable for use in prosthetic heart roller-pumps and does not seem to irritate the vascular system. To date, it has not been tried in the urinary tract.

The outer tube of the urinary valve can be either stainless steel or titanium, both noted for their biological inertness. Teflon can also be considered for this application because of its cost, availability, ease of machining and its tissue compatibility. We can allow a choice here with no difficulty.

Connecting tubings, the control valve body, and the pressure bulb could be made of medical grade silastic, with only one problem: silastic is quite permeable to most of the gases which are feasible for the control system. A search is currently under way for a suitable control medium which will allow us to use silastics.

In lieu of silastic, we can use Lycra for the inner tube and pressure bulb and Viton for the connecting tubing. This, however, makes the implantation as much a study in materials compatibility as it is a valve study.

The pressure bulb must be resilient enough to prevent the urinary valve from being occluded by pressure generated in swelling tissue around the bulb during the immediate post-operative period. It must also be soft enough to be easily compressed by the fingertips or the palm.

To minimize danger from leakage of the control system, the recommended control fluid is dry nitrogen, flushed several times through the valves, tubing and bulb. In the event that Lycra is an unusable material, we may have to switch to a fluorocarbon for the control fluid so that silastic can be substituted.

Delivery of the end item will depend primarily on the availability of materials (silastic, Lycra, etc.). Barring any procurement difficulties, fabrication should be completed within three weeks from receipt of all materials.

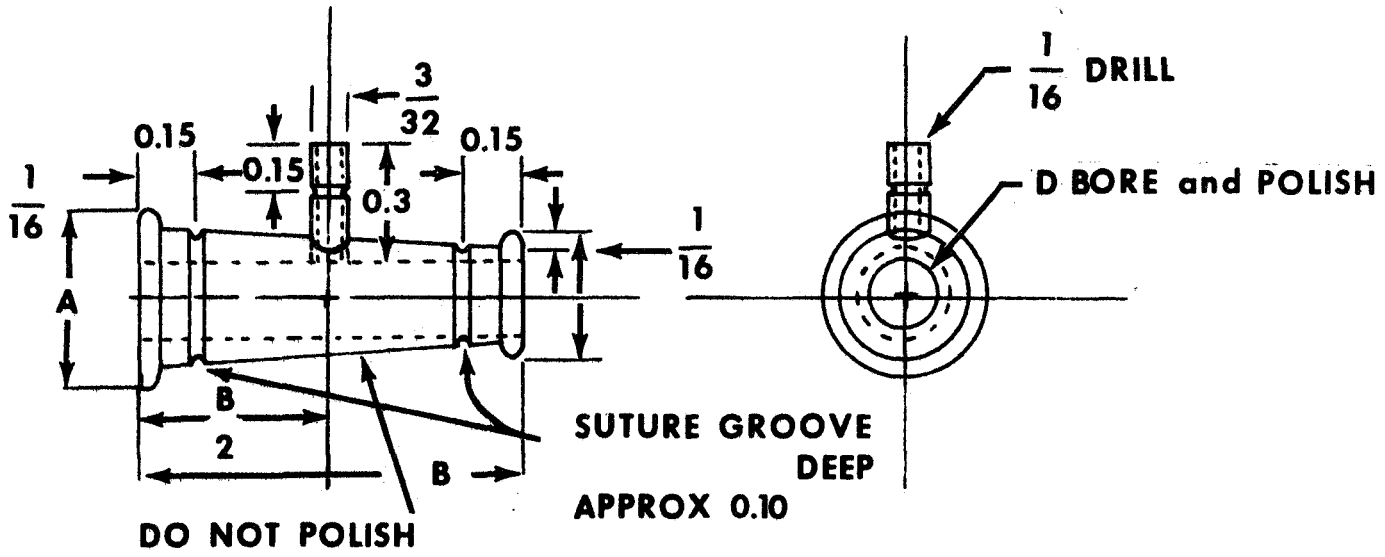
We propose to build 5 urinary valves, having the sizes indicated in the table on the drawing, utilizing Lycra components. We will also construct 2 control valves and 2 pressure bulbs, similarly from Lycra.

The sizes are selected to cover both experimental animals and humans, but liability for human experimentation is left to the problem originator. We do not recommend trials in humans until the feasibility of Lycra in the urinary tract is proven.

Cost Estimate

Materials	$150
Labor (25 man-hours at $10.00/hr.)	250
Total	$400

Each of the valves will be tested in vitro for control pressure required to terminate flow, for opening pressure vs. control pressure, and for leakage of the control system. Documentation of test results will accompany the end item delivery.

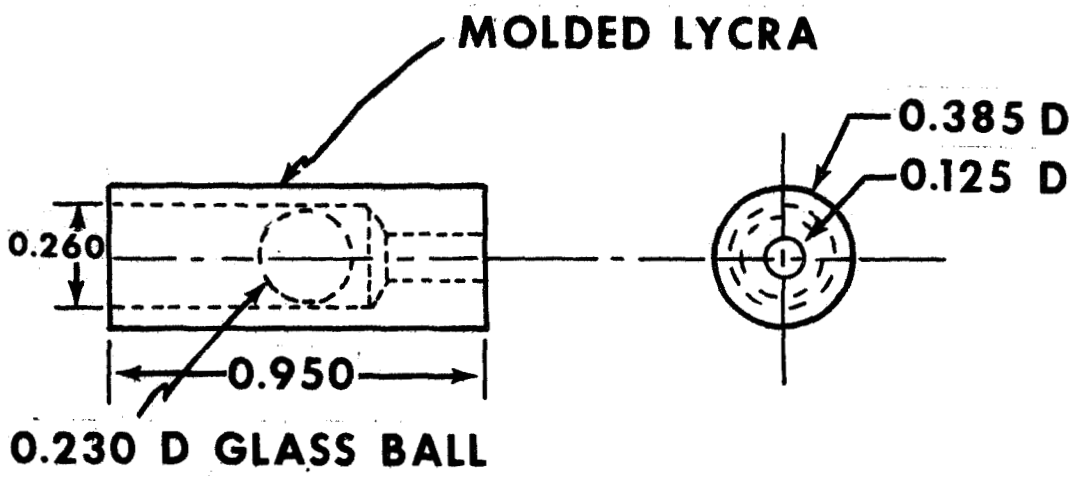


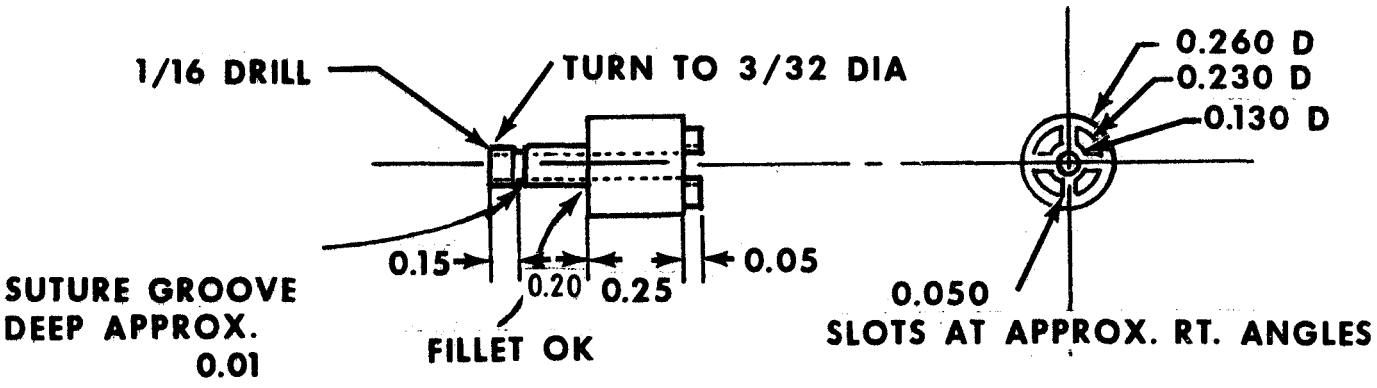
5 PIECES

	A	B	C (INCHES)		D
1 ea					
VALVE #1	0.370	1.00	0.260		3/32
#2	0.395	1.25	0.290		1/8
#3	0.420	1.425	0.325	± 0.005	5/32
#4	0.445	1.60	0.325		5/32
#5	0.470	1.775	0.350		3/16

HAYNES ALLOY 25

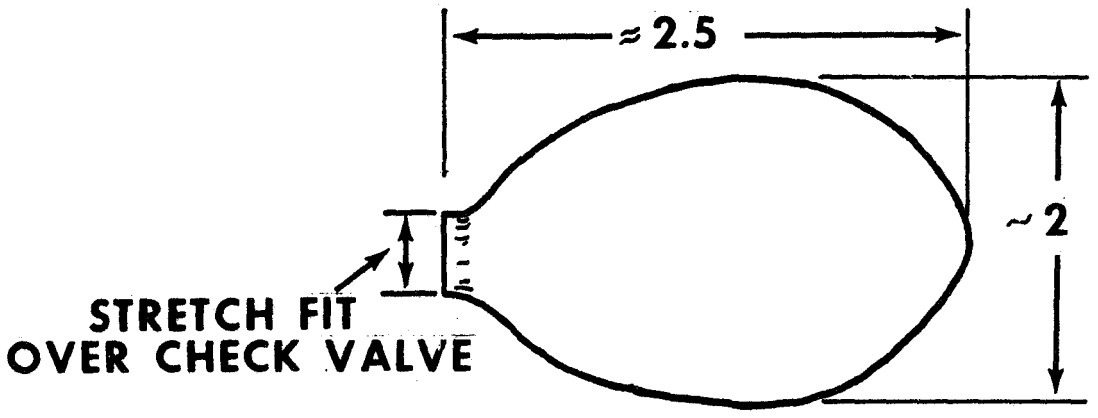
POLISH THIS HOLE


MOLDED LYCRA
0.385 D
0.125 D
0.260
0.950
0.230 D GLASS BALL



DO NOT POLISH

VALVE INSERT - HAYNES ALLOY 25 - 5 PIECES



PRESSURE BULB - COAT TOY BALLOON
WITH LYCRA; REMOVE BALLOON

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